9. 510(k) Summary

DEC 2 0 2002

510(k) Summary of Safety and Effectiveness

Company Name:

Rhythmlink International, LLC
2013 Windsor Drive
Cayce, SC 29033

Phone: 803-926-8080
FDA Registration #: PEND80891

Official Contact Person: Brett L Netherton, President

Summary Date: August 29, 2002

Device Identification:

Proprietary Device Name:
Rhythmlink International Subdermal Needle Electrodes

Generic Device Name:
Subdermal Needle Electrodes

Regulatory Class: Class II
Classification Name: 21 CFR 882.1350, Needle Electrode

This device has not been previously submitted to the FDA.

Predicate Device(s):

510(k) Number: K990015
Manufacturer: Technomed Europe
Trade Name: Various Needle Electrode
Product Code: 89IKT

510(k) Number: K010019
Manufacturer: Nicolet Biomedical
Trade Name: Sterile Subdermal Needle Electrodes
Product Code: 84GXZ

Device Description:

Rhythmlink International Subdermal Needle Electrodes are single patient use, disposable, sterile devices. Electrodes are applied in the study of biopotentials such as electroencephalograph (EEG), electromyograph (EMG), nerve conduction and stimulation/response. Electrodes are invasive as they are placed subcutaneously or in contact with nerve or muscle tissue.

The electrodes consist of a stainless steel needle with a lead wire attached. The lead wires terminate in a safety connector that cannot be connected to an AC power outlet.

The electrodes provide the patient contact device. The electrodes connect to the user's recording, monitoring and stimulation/response equipment. The electrodes are used under the supervision of a physician.

Intended Use:	Rhythmlink International Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.
Technological Characteristics:	The electrodes consist of a formed stainless steel needle with a lead wire attached. The lead wires terminate in a safety connector that cannot be connected to an AC power outlet. The characteristics of Rhythmlink International Subdermal Needle Electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Rhythmlink International, LLC
Brett L. Netherton
President
2013 Windsor Drive
Cayce, South Carolina 29033

Re: K022914
Trade/Device Name: Rhythmlink International Subdermal Needle Electrodes
Regulation Number: 882.1350
Regulation Name: Needle electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: December 4, 2002
Received: December 11, 2002

Dear Mr. Netherton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): SEE BELOW

Device Name: SEE BELOW

Indications For Use:

510(k) Number: K022914

Device Name: Rhythmlink International Subdermal Needle Electrodes

Indications for Use:

Rhythmlink International Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022914